DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dear Panel Member:

Thank you for your willingness to come and participate in the Neurological Devices Advisory Panel meeting scheduled for September 16 and 17, 1999.

FDA is requesting that you provide discussion and comment on a draft guidance document entitled "Guidance Document for Dura Substitute Devices (Draft)". The purpose of this document is to provide information to the sponsor on important preclinical and clinical information, which should be presented in a premarket notification (510(k)) submission for a dura substitute.

Since the turn of the century, a wide variety of both natural and synthetic materials have been used to seal holes in the dura mater. The natural materials have included both processed and unprocessed tissues. Numerous synthetic materials have been used. According to several authors, dura substitutes must have three basic qualities: biocompatibility; the ability to prevent tissue adhesions between the cerebral cortex and overlying soft tissue; and the ability to prevent cerebrospinal fluid (CSF) leakage.

On November15, 1978 FDA issued a proposed rule recommending that dura substitutes be classified as class II (performance standards) products. The proposed rule for classification was based upon the recommendations of the Neurological and Device Classification Panel, a FDA advisory committee. The Panel had made the following recommendations with respect to the classification of dura substitutes:

1. Identification: A dura substitute is a sheet of material that is used to repair the dura mater.
2. Recommended classification: Class II (performance standards). The Panel recommended that establishing a performance standard for this device be a low priority.
3. Summary of reasons for recommendation: The Panel recommended that dura substitutes be classified into class II because the material is required to be biocompatible and is required to maintain a seal to prevent cerebrospinal fluid (CSF) leakage.
4. Summary of data on which the recommendation was based: The Panel members based their recommendation on their clinical experience with dura substitutes.
5. Risks to health: (a) Tissue reaction: The material used in the device may be toxic to surrounding tissue, or may adhere to neural tissue. (b) CSF leakage: If the material does not maintain a seal with the dura, or if defects in the material occur, the CSF may leak out.

On September 4, 1979 (effective date, October 4, 1979) FDA issued a final rule classifying dura substitutes into class II. During the 60-day public comment period prior to rule issuance, no written comments were received.

In this package you will find the draft guidance document and a list of questions that we would like you to consider and be ready to discuss at the Advisory Panel meeting. If you have any questions please contact Ms. Jan Scudeiro, Executive Secretary for the Neurological Devices Panel at 301-594-1184 or myself at 301-594-3090 x194. Again, thank you for your participation.

Sincerely yours,

Peter L. Hudson, Ph.D.
Reviewer
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